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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,694	04/16/2001	John J. Donnelly	18972PCA	5738
7590 10/03/2003			EXAMINER	
Merck & Co., Inc. Patent Department P.O. Box 2000 - RY60-30 Rahway, NJ 07065-0907			MCKELVEY, TERRY ALAN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,694	DONNELLY ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 17-18, drawn to DNA construct, vaccine, and method for protecting against infection, classified in class 435, subclass 320.1 and class 514, subclass 44.

Group I is comprised of multiple inventions which are drawn to the DNA constructs comprising DNA sequences that are biologically, chemically, and functionally distinct, and don't render each other obvious, set forth in claims 4-6, 18, etc. If Group I is elected, applicants must elect a single invention which is drawn to a specific DNA construct to which the claims will be restricted. Note: this restriction is due to the now undue burden to examine claims drawn to more than one sequence in an application.

- II. Claims 12-15 and 25, drawn to method for using an influenza gene to induce immune responses in vivo, classified in class 514, subclass 44.

Group II is comprised of multiple inventions which are drawn to the use of different genes that are biologically,

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chemically, and functionally distinct, and don't render each other obvious, set forth in claim 15, etc. If Group II is elected, applicants must elect a single invention which is drawn to a specific gene to which the claims will be restricted.

Note: this restriction is due to the now undue burden to examine claims drawn to more than one independent gene in an application.

III. Claim 16, drawn to method for inducing immune responses, classified in class 514, subclass 44.

IV. Claims 19-22, drawn to composition comprising multiple DNA constructs, classified in class 514, subclass 44.

V. Claim 23, drawn to expression vector V1 Jns, classified in class 435, subclass 320.1.

VI. Claim 24, drawn to expression vector V1JR, classified in class 435, subclass 320.1.

Claims 1 and 12 link(s) inventions of Groups I and II, drawn to different vectors or genes, respectively. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 12. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled

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to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group IV and Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because claim 19 recites a generic combination. The

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subcombination has separate utility such as vectors to carry immunogenic genes.

Inventions of Groups I and Group V-VI are related as combination and subcombinations. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because other vectors can be used instead of the vectors of Groups V-VI. The subcombination has separate utility such as for replicating DNA (i.e., used as a non-immunogenic vector).

Inventions of methods of Groups I-III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-III comprise steps which are not required for or present in the methods of the other groups. The end result of the methods are different: protecting against infection by human influenza virus by immunization with a known, specific vector (Group I), using a newly isolated influenza gene to induce immune response (Group II), and inducing immune response by introducing a nucleic acid

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that encodes a conserved virus epitope (Group III). Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Group I is comprised of multiple inventions which are drawn to the DNA constructs of claims 4-6, 18, etc. If Group I is elected, applicants must elect a single invention which is drawn to a specific DNA construct to which the claims will be restricted.

Except for the specific relationships described above, the inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I, IV-VI are not specifically used in or made by the methods of Groups I-III.

Because these inventions are distinct for the reasons given above and the search required for Groups I-VI is not required for the other groups because either they are classified separately, or the claimed products and/or methods of each group have product components or method steps not in common with the other groups and thus must be searched for separately, restriction for examination purposes as indicated is proper.

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

September 30, 2003